13406-006WOU1 GZT
FOUNDRY.019VPC2/
pk
AR

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
DANIEL E. ALTMAN
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 MAIN STREET, 14TH FLOOR
IRVINE, CA 92614

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing *(day/month/year)* 04 SEP 2008	
Applicant's or agent's file reference FOUNDRY019V2	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US 08/60922	International filing date *(day/month/year)* 18 April 2008 (18.04.2008)
Applicant THE FOUNDRY, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference FOUNDRY019V2	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US 08/60922	International filing date *(day/month/year)* 18 April 2008 (18.04.2008)	(Earliest) Priority Date *(day/month/year)* 19 April 2007 (19.04.2007)
Applicant THE FOUNDRY, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language**, the international search was carried out on the basis of:
      ☒ the international application in the language in which it was filed.
      ☐ a translation of the international application into ______________ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
   b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).
   c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,
   a. the figure of the **drawings** to be published with the abstract is Figure No. 4
      ☐ as suggested by the applicant.
      ☒ as selected by this Authority, because the applicant failed to suggest a figure.
      ☐ as selected by this Authority, because this figure better characterizes the invention.
   b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/60922

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 18/18 (2008.04)
USPC - 606/33
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
USPC: 606/33

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC(8): A61B18/00 (2008.04)
USPC: 606/32, 1

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WEST (PGPB,USPT,USOC,EPAB,JPAB)
Google (Patents, Scholar, and Web)
Search Terms Used: vacuum temperature cool skin GHz standing wave pattern interference tissue microwave

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/0130711 A1 (PEARSON et al.) 10 July 2003 (10.07.2003), entire document, especially: para [0004], [0053], [0059], [0072], [0074], [0083], [0087], [0114], [0124], [0146], [0147], [0150], [0155], [0156], [0197]	1 5, 6, 11-17, 20, 23, 24, 26
Y		2-4, 7-10, 18, 19, 21, 22, 25, 27
Y	US 2004/0143250 A1 (TREMBLY) 22 July 2004 (22.07.2004), para [0019], [0034]	2-4, 7-10, 27
Y	US 4,378,806 A (HENLEY-COHN) 5 April 1983 (05.04.1983), col. 4, ln 66 - col. 5, ln 11	18, 19, 21, 22, 25

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 August 2008 (29.08.2008)	04 SEP 2008

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:
Lee W. Young
PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: DANIEL E. ALTMAN KNOBBE, MARTENS, OLSON & BEAR, LLP 2040 MAIN STREET, 14TH FLOOR IRVINE, CA 92614	**PCT** WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43*bis*.1)
	Date of mailing (*day/month/year*) 04 SEP 2008
Applicant's or agent's file reference FOUNDRY019V2	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/US 08/60922	18 April 2008 (18.04.2008)	19 April 2007 (19.04.2007)

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61B 18/18 (2008.04)
USPC - 606/33

Applicant THE FOUNDRY, INC.

1. This opinion contains indications relating to the following items:

- [x] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [x] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	29 August 2008 (29.08.2008)	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 08/60922

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
   - [x] the international application in the language in which it was filed.
   - [ ] a translation of the international application into ______________ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. [ ] This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:
   a. type of material
      - [ ] a sequence listing
      - [ ] table(s) related to the sequence listing

   b. format of material
      - [ ] on paper
      - [ ] in electronic form

   c. time of filing/furnishing
      - [ ] contained in the international application as filed
      - [ ] filed together with the international application in electronic form
      - [ ] furnished subsequently to this Authority for the purposes of search

4. [ ] In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY	International application No. PCT/US 08/60922

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	2-4, 6-10, 18, 19, 21, 22, 25, 27	YES
	Claims	1, 5, 11-17, 20, 23, 24, 26	NO
Inventive step (IS)	Claims	NONE	YES
	Claims	1-27	NO
Industrial applicability (IA)	Claims	1-27	YES
	Claims	NONE	NO

2. Citations and explanations:

Claims 1, 5, 11-17, 20, 23, 24, and 26 lack novelty under PCT Article 33(2) as being anticipated by US 2003/0130711 A1 to Pearson et al. (hereinafter "Pearson").

As per claim 1, Pearson teaches a system for the application of microwave energy to a tissue (para [0059]--"various aspects of the invention is particularly beneficial for use in the treatment of tumors and tumorous tissue by ablative therapies such as RF, microwave, laser and chemical ablation. These and related ablative therapies causes disruption of cell membranes resulting in impedance change in the interstitial fluid but only in the affected tissue with minimal or no changes to the surrounding tissue"), comprising:
a signal generator adapted to generate a microwave signal having predetermined characteristics (para [0074]--"In and embodiment the RF power supply can be an RF generator configured to deliver a treatment current 20t for tissue ablation");
an applicator connected to the generator and adapted to apply microwave energy to tissue, the applicator comprising one or more microwave antennas and a tissue interface (para [0053]--""Electrode", "resilient member" and "antenna" are interchangable and refer to a needle or wire for conducting energy to a tissue site"; [0124]--"a microwave power source coupled to a microwave antenna providing microwave energy"; [0146]--"interface between the patients skin and a ground pad or return electrode coupled the RF generators");
a vacuum source connected to the tissue interface (para [0114]--"Tissue aspiration/collection devices 26 can include syringes, vacuum sources"; [0150]--"Alternatively, the fluid delivery device can be coupled to a vacuum source or otherwise be configured to apply negative pressure to suction off fluid from the target tissue into the lumen(s) of the electrode or lumen(s) of the introducer");
a cooling source connected to said tissue interface (para [0114]--"In various embodiments, ports can be configured for...the delivery of cooling...fluids (both liquid and gas) described herein"); and
a controller adapted to control the signal generator, the vacuum source, and the coolant source (para [0056]--""Feedback control device", "control unit", "control resources", "feedback control system", and "controller" are interchangable and refer to a control capable of modulating an ablation parameter, i.e. power, temperature, infusion, etc. The control may be automatically or manually operated").

As per claim 5, Pearson teaches the microwave energy application system of claim 1, as above, and further teaches wherein the microwave antenna comprises an antenna configured to radiate electromagnetic radiation (para [0156]--"Lower electromagnetic frequencies such as RF frequencies (e.g. 1 kHz to 1 MHZ) produce a more localized energy concentration (e.g. current density) with the resulting zone of energy concentration or ablation zone 5az occurring close to the energy delivery electrode/antenna in terms of a lateral distance") polarized such that an E-field component of the electromagnetic radiation is substantially parallel to an outer surface of the tissue (para [0083]--"the alternative conductive pathway can share one or more points in common with the original pathway or be parallel with the original pathway but offset a selectable lateral distance"; [0087]--"impedance sensing members 22m can be arranged in arrays 22a having a variety of geometric arrangements and relationships so as to electrically sample different volumes of tissue 5sv using different conductive pathways").

As per claim 11, Pearson teaches a method of creating a tissue effect in a target tissue layer (para [0059]--"various aspects of the invention is particularly beneficial for use in the treatment of tumors and tumorous tissue by ablative therapies such as RF, microwave, laser and chemical ablation. These and related ablative therapies causes disruption of cell membranes resulting in impedance change in the interstitial fluid but only in the affected tissue with minimal or no changes to the surrounding tissue"), comprising the steps of:
irradiating the target tissue layer and a first tissue layer through a skin surface with electromagnetic energy (para [0004]--"An embodiment of the invention provides an impedance controlled tissue ablation apparatus and method that utilizes impedance determinations, such as localized tissue impedance to optimize the delivery of radio-frequency or other electromagnetic energy to a target tissue site") having predetermined frequency and electric field characteristics (para [0156]--"Lower electromagnetic frequencies such as RF frequencies (e.g. 1 kHz to 1 MHZ) produce a more localized energy concentration (e.g. current density) with the resulting zone of energy concentration or ablation zone 5az occurring close to the energy delivery electrode/antenna in terms of a lateral distance"), wherein the first tissue layer is above the target tissue layer, the first tissue layer being adjacent to a surface of the skin (para [0197]--"Embodiments of the invention can be configured for the treatment of tumor and tissue masses at or beneath a tissue surface in a number of organs"--skin is a tissue); and generating a power loss density profile, wherein the power loss density profile has a peak power loss density in a region of the target tissue layer (para [0147]--"various embodiments of the invention can be configured to optimize...target tissue current density including current density gradients as a function of distance from the electrode").

-----PLEASE SEE SUPPLEMENTAL BOX-----

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 08/60922

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box V(2) Citations and explanations:

As per claim 12, Pearson teaches a method of creating a lesion in a target tissue layer in the absence of cooling (para [0156]--"these and related embodiments provide the benefit of allowing the size, position and shape of the lesion to be precisely controlled and/or titrated in order to meet the therapeutic needs of the target tissue"), wherein the target tissue layer is below a first tissue layer, the first tissue layer being adjacent to a skin surface (para [0197]--"Embodiments of the invention can be configured for the treatment of tumor and tissue masses at or beneath a tissue surface in a number of organs"--skin is a tissue), the method comprising the steps of: irradiating the target tissue layer and a first tissue layer through a skin surface with electromagnetic energy (para [0004]--"An embodiment of the invention provides an impedance controlled tissue ablation apparatus and method that utilizes impedance determinations, such as localized tissue impedance to optimize the delivery of radio-frequency or other electromagnetic energy to a target tissue site") having predetermined frequency and electric field characteristics (para [0156]--"Lower electromagnetic frequencies such as RF frequencies (e.g. 1 kHz to 1 MHZ) produce a more localized energy concentration (e.g. current density), wherein the first tissue layer is above the target tissue layer, the first tissue layer being adjacent to a surface of the skin (para [0197]--"Embodiments of the invention can be configured for the treatment of tumor and tissue masses at or beneath a tissue surface in a number of organs"--skin is a tissue); and
generating a power loss density profile, wherein the power loss density profile has a peak power loss density in a region of the target tissue layer (para [0147]--"various embodiments of the invention can be configured to optimize...target tissue current density including current density gradients as a function of distance from the electrode").

As per claim 13, Pearson teaches a method of generating heat in a target tissue layer wherein the heat is sufficient to create a lesion in or proximate to the target tissue layer (para [0156]--"these and related embodiments provide the benefit of allowing the size, position and shape of the lesion to be precisely controlled and/or titrated in order to meet the therapeutic needs of the target tissue"), wherein the target tissue layer is below a first tissue layer, the first tissue layer being adjacent to a skin surface (para [0197]--"Embodiments of the invention can be configured for the treatment of tumor and tissue masses at or beneath a tissue surface in a number of organs"--skin is a tissue), the method comprising the steps of:
irradiating the target tissue layer and the first tissue layer through the skin surface with electromagnetic energy (para [0004]--"An embodiment of the invention provides an impedance controlled tissue ablation apparatus and method that utilizes impedance determinations, such as localized tissue impedance to optimize the delivery of radio-frequency or other electromagnetic energy to a target tissue site") having predetermined frequency and electric field characteristics (para [0156]--"Lower electromagnetic frequencies such as RF frequencies (e.g. 1 kHz to 1 MHZ) produce a more localized energy concentration (e.g. current density); and
generating a power loss density profile wherein the power loss density profile has a peak power loss density in a region of the target tissue layer (para [0147]--"various embodiments of the invention can be configured to optimize...target tissue current density including current density gradients as a function of distance from the electrode").

As per claim 14, Pearson teaches a method of generating heat in a target tissue layer in the absence of cooling wherein the heat is sufficient to create a tissue effect in or proximate to the target tissue layer (para [0059]--"various aspects of the invention is particularly beneficial for use in the treatment of tumors and tumorous tissue by ablative therapies such as RF, microwave, laser and chemical ablation. These and related ablative therapies causes disruption of cell membranes resulting in impedance change in the interstitial fluid but only in the affected tissue with minimal or no changes to the surrounding tissue"), wherein the target tissue layer is below a first tissue layer, the first tissue layer being adjacent to a skin surface (para [0197]--"Embodiments of the invention can be configured for the treatment of tumor and tissue masses at or beneath a tissue surface in a number of organs"--skin is a tissue), the method comprising the steps of: irradiating the target tissue layer and the first tissue layer through the skin surface with electromagnetic energy (para [0004]--"An embodiment of the invention provides an impedance controlled tissue ablation apparatus and method that utilizes impedance determinations, such as localized tissue impedance to optimize the delivery of radio-frequency or other electromagnetic energy to a target tissue site") having predetermined frequency and electric field characteristics (para [0156]--"Lower electromagnetic frequencies such as RF frequencies (e.g. 1 kHz to 1 MHZ) produce a more localized energy concentration (e.g. current density); and
generating a power loss density profile wherein the power loss density profile has a peak power loss density in a region of the target tissue layer (para [0147]--"various embodiments of the invention can be configured to optimize...target tissue current density including current density gradients as a function of distance from the electrode").

As per claim 15, Pearson teaches a method of generating a temperature profile in tissue wherein the temperature profile has a peak in a target tissue layer (para [0155]--"In an embodiment, the sensor can be selected to measure temperature...a feedback signal from a temperature sensor or temperature calculation device...determines that a desired cell necrosis temperature is exceeded, then an appropriate signal is sent to the controller which then regulates the amount of electromagnetic energy delivered to the electrodes"), wherein the target tissue layer is below a first tissue layer, the first tissue layer being adjacent to a skin surface (para [0197]--"Embodiments of the invention can be configured for the treatment of tumor and tissue masses at or beneath a tissue surface in a number of organs"--skin is a tissue), the method comprising the steps of:
irradiating the target tissue layer and the first tissue layer through the skin surface with electromagnetic energy (para [0004]--"An embodiment of the invention provides an impedance controlled tissue ablation apparatus and method that utilizes impedance determinations, such as localized tissue impedance to optimize the delivery of radio-frequency or other electromagnetic energy to a target tissue site") having predetermined frequency and electric field characteristics (para [0156]--"Lower electromagnetic frequencies such as RF frequencies (e.g. 1 kHz to 1 MHZ) produce a more localized energy concentration (e.g. current density); and
generating a power loss density profile wherein the power loss density profile has a peak power loss density in a region of the target tissue layer (para [0147]--"various embodiments of the invention can be configured to optimize...target tissue current density including current density gradients as a function of distance from the electrode").

----------PLEASE SEE SUPPLEMENTAL BOX----------

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box V(2) Citations and explanations:

As per claim 16, Pearson teaches a method of generating a temperature profile in tissue in the absence of cooling wherein the temperature profile has a peak in a target tissue layer (para [0155]--"In an embodiment, the sensor can be selected to measure temperature...a feedback signal from a temperature sensor or temperature calculation device...determines that a desired cell necrosis temperature is exceeded, then an appropriate signal is sent to the controller which then regulates the amount of electromagnetic energy delivered to the electrodes"), wherein the target tissue layer is below a first tissue layer, the first tissue layer being adjacent to a skin surface (para [0197]--"Embodiments of the invention can be configured for the treatment of tumor and tissue masses at or beneath a tissue surface in a number of organs"--skin is a tissue), the method comprising the steps of:
irradiating the target tissue layer and the first tissue layer through the skin surface with electromagnetic energy (para [0004]--"An embodiment of the invention provides an impedance controlled tissue ablation apparatus and method that utilizes impedance determinations, such as localized tissue impedance to optimize the delivery of radio-frequency or other electromagnetic energy to a target tissue site") having predetermined frequency and electric field characteristics (para [0156]--"Lower electromagnetic frequencies such as RF frequencies (e.g. 1 kHz to 1 MHZ) produce a more localized energy concentration (e.g. current density); and
generating a power loss density profile wherein the power loss density profile has a peak power loss density in a region of the target tissue layer (para [0147]--"various embodiments of the invention can be configured to optimize...target tissue current density including current density gradients as a function of distance from the electrode").

As per claim 17, Pearson teaches a method of creating a lesion in a first layer of tissue (para [0156]--"these and related embodiments provide the benefit of allowing the size, position and shape of the lesion to be precisely controlled and/or titrated in order to meet the therapeutic needs of the target tissue"), the first layer having an upper portion adjacent an external surface of the skin and a lower portion adjacent a second layer of the skin (para [0197]--"Embodiments of the invention can be configured for the treatment of tumor and tissue masses at or beneath a tissue surface in a number of organs"--skin is a tissue), the method comprising the steps of:
exposing the external surface of the skin to microwave energy having a predetermined power, frequency, and electric field orientation (para [0059]--"various aspects of the invention is particularly beneficial for use in the treatment of tumors and tumorous tissue by ablative therapies such as RF, microwave, laser and chemical ablation. These and related ablative therapies causes disruption of cell membranes resulting in impedance change in the interstitial fluid but only in the affected tissue with minimal or no changes to the surrounding tissue");
generating an energy density profile having a peak in the lower portion of the first layer (para [0147]--"various embodiments of the invention can be configured to optimize...target tissue current density including current density gradients as a function of distance from the electrode"); and
continuing to expose the external surface of the skin to the microwave energy for a time sufficient to create a lesion, wherein the lesion begins in the peak energy density region (para [0156]--"these and related embodiments provide the benefit of allowing the size, position and shape of the lesion to be precisely controlled and/or titrated in order to meet the therapeutic needs of the target tissue"; [0147]--"various embodiments of the invention can be configured to optimize...target tissue current density including current density gradients as a function of distance from the electrode").

As per claim 20, Pearson teaches a method of creating a lesion in a dermal layer of the skin, the dermal layer having an upper portion adjacent an external surface of the skin and a lower portion adjacent a subdermal layer of the skin (para [0156]--"these and related embodiments provide the benefit of allowing the size, position and shape of the lesion to be precisely controlled and/or titrated in order to meet the therapeutic needs of the target tissue"), the method comprising the steps of:
exposing the external surface to microwave energy having a predetermined power, frequency, and electric field orientation (para [0059]--"various aspects of the invention is particularly beneficial for use in the treatment of tumors and tumorous tissue by ablative therapies such as RF, microwave, laser and chemical ablation. These and related ablative therapies causes disruption of cell membranes resulting in impedance change in the interstitial fluid but only in the affected tissue with minimal or no changes to the surrounding tissue");
generating a peak energy density region in the lower portion of the dermal layer (para [0147]--"various embodiments of the invention can be configured to optimize...target tissue current density including current density gradients as a function of distance from the electrode");
and continuing to radiate the skin with the microwave energy for a time sufficient to create a lesion, wherein the lesion begins in the peak energy density region (para [0156]--"these and related embodiments provide the benefit of allowing the size, position and shape of the lesion to be precisely controlled and/or titrated in order to meet the therapeutic needs of the target tissue"; [0147]--"various embodiments of the invention can be configured to optimize...target tissue current density including current density gradients as a function of distance from the electrode").

As per claim 23, Pearson teaches a method of heating a tissue structure located in or near a target tissue layer (para [0059]--"various aspects of the invention is particularly beneficial for use in the treatment of tumors and tumorous tissue by ablative therapies such as RF, microwave, laser and chemical ablation. These and related ablative therapies causes disruption of cell membranes resulting in impedance change in the interstitial fluid but only in the affected tissue with minimal or no changes to the surrounding tissue"), wherein the target tissue layer is below a first tissue layer, the first tissue layer being adjacent a skin surface (para [0197]--"Embodiments of the invention can be configured for the treatment of tumor and tissue masses at or beneath a tissue surface in a number of organs"--skin is a tissue), the method comprising the steps of:
irradiating the target tissue layer and the first tissue layer through the skin surface with electromagnetic energy (para [0004]--"An embodiment of the invention provides an impedance controlled tissue ablation apparatus and method that utilizes impedance determinations, such as localized tissue impedance to optimize the delivery of radio-frequency or other electromagnetic energy to a target tissue site") having predetermined frequency and electric field characteristics (para [0156]--"Lower electromagnetic frequencies such as RF frequencies (e.g. 1 kHz to 1 MHZ) produce a more localized energy concentration (e.g. current density); and
generating a power loss density profile wherein the power loss density profile has a peak power loss density in a region of the target tissue layer (para [0147]--"various embodiments of the invention can be configured to optimize...target tissue current density including current density gradients as a function of distance from the electrode").

------------------------------PLEASE SEE SUPPLEMENTAL BOX------------------------------

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box V(2) Citations and explanations:

As per claim 24, Pearson teaches a method of raising the temperature of at least a portion of a tissue structure (para [0059]--"various aspects of the invention is particularly beneficial for use in the treatment of tumors and tumorous tissue by ablative therapies such as RF, microwave, laser and chemical ablation. These and related ablative therapies causes disruption of cell membranes resulting in impedance change in the interstitial fluid but only in the affected tissue with minimal or no changes to the surrounding tissue") located below an interface between a dermal layer and subdermal layer in skin, the dermal layer having an upper portion adjacent an external surface of the skin and a lower portion adjacent a subdermal region of the skin, the method comprising the steps of:
irradiating the skin with microwave energy having a predetermined power, frequency and e-field orientation (para [0059]--"various aspects of the invention is particularly beneficial for use in the treatment of tumors and tumorous tissue by ablative therapies such as RF, microwave, laser and chemical ablation. These and related ablative therapies causes disruption of cell membranes resulting in impedance change in the interstitial fluid but only in the affected tissue with minimal or no changes to the surrounding tissue");

generating a peak energy density region in the lower portion of the dermal layer (para [0147]--"various embodiments of the invention can be configured to optimize...target tissue current density including current density gradients as a function of distance from the electrode");
initiating a lesion in the peak energy density region by dielectric heating of tissue in the peak energy density region (para [0156]--"these and related embodiments provide the benefit of allowing the size, position and shape of the lesion to be precisely controlled and/or titrated in order to meet the therapeutic needs of the target tissue");
enlarging the lesion, wherein the lesion is enlarged, at least in part, by conduction of heat from the peak energy density region to surrounding tissue (para [0156]--"these and related embodiments provide the benefit of allowing the size, position and shape of the lesion to be precisely controlled and/or titrated in order to meet the therapeutic needs of the target tissue");
removing heat from the skin surface and at least a portion of the upper portion of the dermal layer (para [0155]--"In an embodiment, the sensor can be selected to measure temperature...a feedback signal from a temperature sensor or temperature calculation device...determines that a desired cell necrosis temperature is exceeded, then an appropriate signal is sent to the controller which then regulates the amount of electromagnetic energy delivered to the electrodes"); and
continuing to radiate the skin with the microwave energy for a time sufficient to extend the lesion past the interface and into the subdermal layer (para [0156]--"these and related embodiments provide the benefit of allowing the size, position and shape of the lesion to be precisely controlled and/or titrated in order to meet the therapeutic needs of the target tissue").

As per claim 26, Pearson teaches a method of controlling the application of microwave energy to tissue (para [0059]--"various aspects of the invention is particularly beneficial for use in the treatment of tumors and tumorous tissue by ablative therapies such as RF, microwave, laser and chemical ablation. These and related ablative therapies causes disruption of cell membranes resulting in impedance change in the interstitial fluid but only in the affected tissue with minimal or no changes to the surrounding tissue"), the method comprising the steps of: generating a microwave signal having predetermined characteristics (para [0059]--"various aspects of the invention is particularly beneficial for use in the treatment of tumors and tumorous tissue by ablative therapies such as RF, microwave, laser and chemical ablation. These and related ablative therapies causes disruption of cell membranes resulting in impedance change in the interstitial fluid but only in the affected tissue with minimal or no changes to the surrounding tissue");
applying the microwave energy to tissue, through a microwave antenna and a tissue interface operably connected to the microwave antenna (para [0053]--""Electrode", "resilient member" and "antenna" are interchangable and refer to a needle or wire for conducting energy to a tissue site"; [0124]--"a microwave power source coupled to a microwave antenna providing microwave energy"; [0146]--"interface between the patients skin and a ground pad or return electrode coupled the RF generators");
supplying a vacuum pressure to the tissue interface (para [0114]--"Tissue aspiration/collection devices 26 can include syringes, vacuum sources"; [0150]--"Alternatively, the fluid delivery device can be coupled to a vacuum source or otherwise be configured to apply negative pressure to suction off fluid from the target tissue into the lumen(s) of the electrode or lumen(s) of the introducer"); and
supplying cooling fluid to the tissue interface (para [0114]--"In various embodiments, ports can be configured for...the delivery of cooling...fluids (both liquid and gas) described herein").

Claim 6 lacks an inventive step under PCT Article 33(3) as being obvious over Pearson

As per claim 6, Pearson teaches the microwave energy application system of claim 1, as above, and further teaches wherein the controller is configured such that the system delivers energy such that a peak power loss density profile is created in the second layer (para [0147]--"various embodiments of the invention can be configured to optimize...target tissue current density including current density gradients as a function of distance from the electrode"). Although Pearson does not specifically teach wherein the tissue comprises a first layer and a second layer, the second layer below the first layer, Pearson does teach wherein a component of the system can penetrate tissue, therefore accessing the vertical layers of the tissue (para [0072]--"The electrode distal end may be sufficiently sharp to penetrate tissue including fibrous and/or encapsulated tumor masses, bone, cartilage and muscle"). Accordingly, it would have been obvious to one skilled in the art, without undue experimentation, to utilize the teachings of Pearson to derive wherein the tissue comprises a first layer and a second layer, the second layer below the first layer.

Claims 2-4, 7-10, and 27 lack an inventive step under PCT Article 33(3) as being obvious over Pearson, in view of US 2004/0143250 A1 (Trembly).

As per claim 2, Pearson teaches the microwave energy application system of claim 1, as above. However, Pearson does not specifically teach wherein the microwave signal has a frequency in the range of between about 4 GHz and about 10 GHz. Trembly teaches wherein the microwave signal has a frequency in the range of between about 4 GHz and about 10 GHz (para [0034]--"the term "microwave" is intended to encompass radiant electrical energy oscillating at frequencies ranging from about 100 MHz to about 10 GigaHz"). It would have been obvious to one of skill in the art to combine the microwave signal frequency of Trembly to the system of Pearson because both Pearson and Trembly teach the use of microwave energy for tissue treatment. Further, Pearson teaches the use of microwave energy in the GHz range (para [0124]--"providing microwave energy in the frequency range from about 915 MHz to about 2.45 GHz"), while Trembly teaches the specific GHz range as claimed.

----------PLEASE SEE SUPPLEMENTAL BOX----------

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box V(2) Citations and explanations:

As per claim 3, Pearson and Trembly teach the microwave energy application system of claim 2, as above, and Trembly further teaches wherein the microwave signal has a frequency in the range of between about 5 GHz and about 6.5 GHz (para [0034]--"the term "microwave" is intended to encompass radiant electrical energy oscillating at frequencies ranging from about 100 MHz to about 10 GigaHz").

As per claim 4, Pearson and Trembly teach the microwave energy application system of claim 3, as above, and Trembly further teaches wherein the microwave signal has a frequency of about 5.8 GHz (para [0034]--"the term "microwave" is intended to encompass radiant electrical energy oscillating at frequencies ranging from about 100 MHz to about 10 GigaHz").

As per claim 7, Pearson teaches an apparatus for delivering microwave energy to target tissue (para [0059]--"various aspects of the invention is particularly beneficial for use in the treatment of tumors and tumorous tissue by ablative therapies such as RF, microwave, laser and chemical ablation. These and related ablative therapies causes disruption of cell membranes resulting in impedance change in the interstitial fluid but only in the affected tissue with minimal or no changes to the surrounding tissue"), the apparatus comprising:
a tissue interface (para [0146]--"interface between the patients skin and a ground pad or return electrode coupled the RF generators");
a microwave energy delivery device (para [0124]--"a microwave power source coupled to a microwave antenna providing microwave energy"; and a cooling fluid positioned between the cooling element and the microwave delivery device (para [0114]--"In various embodiments, ports can be configured for...the delivery of cooling...fluids (both liquid and gas) described herein").

However, Pearson does not specifically teach a cooling element positioned between the tissue interface and the microwave energy device, the cooling element comprising a cooling plate positioned at the tissue interface; the cooling fluid having a dielectric constant greater than a dielectric constant of the cooling element. Trembly teaches a cooling element positioned between the tissue interface and the microwave energy device, the cooling element comprising a cooling plate positioned at the tissue interface (para [0019]--"A cooling system may be configured to cool the applicator during keratoplasty operations without flowing coolant beneath the bottom surface 116. For example, the cooling system may comprise a Peltier effect or thermoelectric cooling device"); the cooling fluid having a dielectric constant greater than a dielectric constant of the cooling element. It would have been obvious to one of skill in the art to combine the cooling element having a cooling plate of Trembly to the system of Pearson because both Pearson (para [0114]) and Trembly (para [0019]) teach cooling tissue treated by microwave energy.

As per claim 8, Pearson teaches an apparatus for delivering microwave energy to a target region in tissue (para [0059]--"various aspects of the invention is particularly beneficial for use in the treatment of tumors and tumorous tissue by ablative therapies such as RF, microwave, laser and chemical ablation. These and related ablative therapies causes disruption of cell membranes resulting in impedance change in the interstitial fluid but only in the affected tissue with minimal or no changes to the surrounding tissue"), the apparatus comprising: a tissue interface having a tissue acquisition chamber (para [0114]--"Tissue aspiration/collection devices 26 can include syringes, vacuum sources coupled to a filter or collection chamber/bag"); and a microwave energy delivery device having a microwave antenna (para [0053]--""Electrode", "resilient member" and "antenna" are interchangable and refer to a needle or wire for conducting energy to a tissue site"; [0124]--"a microwave power source coupled to a microwave antenna providing microwave energy"; [0146]--"interface between the patients skin and a ground pad or return electrode coupled the RF generators").

However, Pearson does not specifically teach a cooling element having a cooling plate. Trembly teaches a cooling element having a cooling plate (para [0019]--"A cooling system may be configured to cool the applicator during keratoplasty operations without flowing coolant beneath the bottom surface 116. For example, the cooling system may comprise a Peltier effect or thermoelectric cooling device"). It would have been obvious to one of skill in the art to combine the cooling element having a cooling plate of Trembly to the system of Pearson because both Pearson (para [0114]) and Trembly (para [0019]) teach cooling tissue treated by microwave energy.

As per claim 9, Pearson teaches an apparatus for delivering microwave energy to a target region in tissue (para [0059]--"various aspects of the invention is particularly beneficial for use in the treatment of tumors and tumorous tissue by ablative therapies such as RF, microwave, laser and chemical ablation. These and related ablative therapies causes disruption of cell membranes resulting in impedance change in the interstitial fluid but only in the affected tissue with minimal or no changes to the surrounding tissue"), the apparatus comprising: a vacuum chamber adapted to elevate tissue including the target region (para [0114]--"Tissue aspiration/collection devices 26 can include syringes, vacuum sources coupled to a filter or collection chamber/bag") and bring the tissue into contact with a [coolant], adapted to contact a skin surface above the target region, cool the skin surface (para [0114]--"In various embodiments, ports can be configured for...the delivery of cooling...fluids (both liquid and gas); and a microwave antenna configured to deliver sufficient energy to the target region to create a thermal effect (para [0053]--""Electrode", "resilient member" and "antenna" are interchangable and refer to a needle or wire for conducting energy to a tissue site"; [0124]--"a microwave power source coupled to a microwave antenna providing microwave energy"; [0146]--"interface between the patients skin and a ground pad or return electrode coupled the RF generators").

However, Pearson does not specifically teach a cooling plate and physically separate the skin tissue from the microwave energy delivery device. Trembly teaches a cooling plate (para [0019]--"A cooling system may be configured to cool the applicator during keratoplasty operations without flowing coolant beneath the bottom surface 116. For example, the cooling system may comprise a Peltier effect or thermoelectric cooling device") and physically separate the skin tissue from the microwave energy delivery device (para [0045]--"a bottom dielectric layer 318 may protect cornea 302 from deleterious temperature effects of electrical conduction current that, otherwise, would flow into cornea 302 from the tubes 306 and 308. The bottom dielectric layer 318 may separate bottom surface 304 from cornea 302. The dielectric layer 318 may be thin enough to minimize interference with microwave emissions and thick enough to prevent superficial deposition of electrical energy by flow of conduction current"). It would have been obvious to one of skill in the art to combine the cooling plate of Trembly to the system of Pearson because both Pearson (para [0114]) and Trembly (para [0019]) teach cooling tissue treated by microwave energy, and separating layers would provide a more effective means to protect adjacent tissue from ablation.

----------PLEASE SEE SUPPLEMENTAL BOX----------

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box V(2) Citations and explanations:

As per claim 10, Pearson teaches a system for coupling microwave energy into tissue (para [0059]--"various aspects of the invention is particularly beneficial for use in the treatment of tumors and tumorous tissue by ablative therapies such as RF, microwave, laser and chemical ablation. These and related ablative therapies causes disruption of cell membranes resulting in impedance change in the interstitial fluid but only in the affected tissue with minimal or no changes to the surrounding tissue"), the system comprising:
a microwave antenna (para [0053]--""Electrode", "resilient member" and "antenna" are interchangable and refer to a needle or wire for conducting energy to a tissue site"; [0124]--"a microwave power source coupled to a microwave antenna providing microwave energy"; [0146]--"interface between the patients skin and a ground pad or return electrode coupled the RF generators");
a fluid chamber positioned between the microwave antenna and the tissue (para [0053]--""Electrode", "resilient member" and "antenna" are interchangable and refer to a needle or wire for conducting energy to a tissue site"; [0124]--"a microwave power source coupled to a microwave antenna providing microwave energy"; [0146]--"interface between the patients skin and a ground pad or return electrode coupled the RF generators").

However, Pearson does not specifically teach a cooling plate. Trembly teaches a cooling plate (para [0019]--"A cooling system may be configured to cool the applicator during keratoplasty operations without flowing coolant beneath the bottom surface 116. For example, the cooling system may comprise a Peltier effect or thermoelectric cooling device"). It would have been obvious to one of skill in the art to combine the cooling plate of Trembly to the system of Pearson because both Pearson (para [0114]) and Trembly (para [0019]) teach cooling tissue treated by microwave energy.

As per claim 27, Pearson teaches a method of positioning tissue prior to treating the tissue using radiated electromagnetic energy, the method comprising:
positioning a tissue interface adjacent a skin surface (para [0058]);
engaging the skin surface in a tissue chamber of the tissue interface (para [0114]--"Tissue aspiration/collection devices 26 can include syringes, vacuum sources coupled to a filter or collection chamber/bag"); and
holding the skin surface in the tissue chamber (para [0114]--"Tissue aspiration/collection devices 26 can include syringes, vacuum sources coupled to a filter or collection chamber/bag").

However, Pearson does not specifically teach substantially separating a layer comprising at least one layer of the skin from a muscle layer below the skin. Trembly does teach substantially separating a layer comprising at least one layer of the skin from a muscle layer below the skin (para [0045]--"a bottom dielectric layer 318 may protect cornea 302 from deleterious temperature effects of electrical conduction current that, otherwise, would flow into cornea 302 from the tubes 306 and 308. The bottom dielectric layer 318 may separate bottom surface 304 from cornea 302. The dielectric layer 318 may be thin enough to minimize interference with microwave emissions and thick enough to prevent superficial deposition of electrical energy by flow of conduction current"). It would have been obvious to one of skill in the art to combine the cooling plate of Trembly to the system of Pearson because both Pearson (para [0114]) and Trembly (para [0019]) teach cooling tissue treated by microwave energy, and separating layers would provide a more effective means to protect adjacent tissue from ablation.

Claims 18, 19, 21, 22, and 25 lack an inventive step under PCT Article 33(3) as being obvious over Pearson, in view of US 4,378,806 A (Henley-Cohn).

As per claim 18, Pearson teaches a method of creating a lesion in the skin wherein the skin has at least an external surface, a first layer below the external surface and a second layer (para [0156]--"these and related embodiments provide the benefit of allowing the size, position and shape of the lesion to be precisely controlled and/or titrated in order to meet the therapeutic needs of the target tissue"), the method comprising the steps of:
positioning a device adapted to radiate electromagnetic energy adjacent the external surface (para [0004]--"An embodiment of the invention provides an impedance controlled tissue ablation apparatus and method that utilizes impedance determinations, such as localized tissue impedance to optimize the delivery of radio-frequency or other electromagnetic energy to a target tissue site");
radiating electromagnetic energy from the device (para [0004]--"An embodiment of the invention provides an impedance controlled tissue ablation apparatus and method that utilizes impedance determinations, such as localized tissue impedance to optimize the delivery of radio-frequency or other electromagnetic energy to a target tissue site"), the microwave energy having an electric field component which is substantially parallel to a region of the external surface (para [0083]--"the alternative conductive pathway can share one or more points in common with the original pathway or be parallel with the original pathway but offset a selectable lateral distance"; [0087]--"impedance sensing members 22m can be arranged in arrays 22a having a variety of geometric arrangements and relationships so as to electrically sample different volumes of tissue 5sv using different conductive pathways").

However, Pearson does not specifically teach generating a standing wave pattern in the first layer, the standing wave pattern having a constructive interference peak in the first layer, wherein a distance from the constructive interference peak to the skin surface is greater than a distance from the constructive interference peak to an interface between the first layer and the second layer. Henley-Cohn does teach generating a standing wave pattern in the first layer, the standing wave pattern having a constructive interference peak in the first layer, wherein a distance from the constructive interference peak to the skin surface is greater than a distance from the constructive interference peak to an interface between the first layer and the second layer (col. 4, ln 66 - col. 5, ln 11). It would have been obvious to one of skill in the art to combine the standing wave pattern of Henley-Cohn to the system of Pearson to provide an apparatus for treating tissue using microwave energy that preferentially heats a target site (ie: tumor), "without an adverse effect on tissue surround the tumor," as taught by Henley-Cohn (col. 5, ln 10-11).

----------PLEASE SEE SUPPLEMENTAL BOX----------

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box V(2) Citations and explanations:

As per claim 19, Pearson teaches a method of creating a temperature gradient in the skin wherein the skin has at least an external surface, a first layer below the external surface and a second layer (para [0159]--"Another benefit, of these and related embodiments, is the ability to produce an energy or thermal gradient within a target tissue site"), the method comprising the steps of:
positioning a device adapted to radiate electromagnetic energy adjacent the external surface (para [0004]--"An embodiment of the invention provides an impedance controlled tissue ablation apparatus and method that utilizes impedance determinations, such as localized tissue impedance to optimize the delivery of radio-frequency or other electromagnetic energy to a target tissue site");
radiating electromagnetic energy from the device, the microwave energy having an electric field component which is substantially parallel to a region of the external surface (para [0083]--"the alternative conductive pathway can share one or more points in common with the original pathway or be parallel with the original pathway but offset a selectable lateral distance"; [0087]--"impedance sensing members 22m can be arranged in arrays 22a having a variety of geometric arrangements and relationships so as to electrically sample different volumes of tissue 5sv using different conductive pathways").

However, Pearson does not specifically teach generating a standing wave pattern in the first layer, the standing wave pattern having a constructive interference peak in the first layer, wherein a distance from the constructive interference peak to the skin surface is greater than a distance from the constructive interference peak to an interface between the first layer and the second layer. Henley-Cohn does teach generating a standing wave pattern in the first layer, the standing wave pattern having a constructive interference peak in the first layer, wherein a distance from the constructive interference peak to the skin surface is greater than a distance from the constructive interference peak to an interface between the first layer and the second layer (col. 4, ln 66 - col. 5, ln 11). It would have been obvious to one of skill in the art to combine the standing wave pattern of Henley-Cohn to the system of Pearson to provide an apparatus for treating tissue using microwave energy that preferentially heats a target site (ie: tumor), "without an adverse effect on tissue surround the tumor," as taught by Henley-Cohn (col. 5, ln 10-11).

As per claim 21, Pearson teaches a method of creating a lesion in a dermal layer of the skin wherein the skin has at least a dermal layer and a subdermal layer (para [0156]--"these and related embodiments provide the benefit of allowing the size, position and shape of the lesion to be precisely controlled and/or titrated in order to meet the therapeutic needs of the target tissue"), the method comprising the steps of: positioning a device adapted to radiate microwave energy adjacent an external surface of the skin (para [0004]--"An embodiment of the invention provides an impedance controlled tissue ablation apparatus and method that utilizes impedance determinations, such as localized tissue impedance to optimize the delivery of radio-frequency or other electromagnetic energy to a target tissue site"); and radiating microwave energy having an electric field component which is substantially parallel to a region of the external surface of the skin above the dermal layer (para [0083]--"the alternative conductive pathway can share one or more points in common with the original pathway or be parallel with the original pathway but offset a selectable lateral distance"; [0087]--"impedance sensing members 22m can be arranged in arrays 22a having a variety of geometric arrangements and relationships so as to electrically sample different volumes of tissue 5sv using different conductive pathways").

However, Pearson does not specifically teach generating a standing wave pattern in the first layer, the standing wave pattern having a constructive interference peak in the first layer, wherein a distance from the constructive interference peak to the skin surface is greater than a distance from the constructive interference peak to an interface between the first layer and the second layer. Henley-Cohn does teach generating a standing wave pattern in the first layer, the standing wave pattern having a constructive interference peak in the first layer, wherein a distance from the constructive interference peak to the skin surface is greater than a distance from the constructive interference peak to an interface between the first layer and the second layer (col. 4, ln 66 - col. 5, ln 11). It would have been obvious to one of skill in the art to combine the standing wave pattern of Henley-Cohn to the system of Pearson to provide an apparatus for treating tissue using microwave energy that preferentially heats a target site (ie: tumor), "without an adverse effect on tissue surround the tumor," as taught by Henley-Cohn (col. 5, ln 10-11).

As per claim 22, Pearson teaches a method of creating a lesion in a dermal layer of the skin wherein the skin has at least a dermal layer and a subdermal layer (para [0156]--"these and related embodiments provide the benefit of allowing the size, position and shape of the lesion to be precisely controlled and/or titrated in order to meet the therapeutic needs of the target tissue"), the method comprising the steps of: positioning a device adapted to radiate microwave energy adjacent an external surface of the skin (para [0004]--"An embodiment of the invention provides an impedance controlled tissue ablation apparatus and method that utilizes impedance determinations, such as localized tissue impedance to optimize the delivery of radio-frequency or other electromagnetic energy to a target tissue site");
radiating microwave energy having an electric field component which is substantially parallel to a region of the external surface of the skin above the dermal layer (para [0083]--"the alternative conductive pathway can share one or more points in common with the original pathway or be parallel with the original pathway but offset a selectable lateral distance"; [0087]--"impedance sensing members 22m can be arranged in arrays 22a having a variety of geometric arrangements and relationships so as to electrically sample different volumes of tissue 5sv using different conductive pathways"); and heating the lower portion of the dermal region using the radiated microwave energy to create the lesion (para [0059]--"various aspects of the invention is particularly beneficial for use in the treatment of tumors and tumorous tissue by ablative therapies such as RF, microwave, laser and chemical ablation. These and related ablative therapies causes disruption of cell membranes resulting in impedance change in the interstitial fluid but only in the affected tissue with minimal or no changes to the surrounding tissue"; [0156]--"these and related embodiments provide the benefit of allowing the size, position and shape of the lesion to be precisely controlled and/or titrated in order to meet the therapeutic needs of the target tissue").

--PLEASE SEE SUPPLEMENTAL BOX--

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 08/60922

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box V(2) Citations and explanations:

However, Pearson does not specifically teach generating a standing wave pattern in the first layer, the standing wave pattern having a constructive interference peak in the first layer, wherein a distance from the constructive interference peak to the skin surface is greater than a distance from the constructive interference peak to an interface between the first layer and the second layer. Henley-Cohn does teach generating a standing wave pattern in the first layer, the standing wave pattern having a constructive interference peak in the first layer, wherein a distance from the constructive interference peak to the skin surface is greater than a distance from the constructive interference peak to an interface between the first layer and the second layer (col. 4, ln 66 - col. 5, ln 11). It would have been obvious to one of skill in the art to combine the standing wave pattern of Henley-Cohn to the system of Pearson to provide an apparatus for treating tissue using microwave energy that preferentially heats a target site (ie: tumor), "without an adverse effect on tissue surround the tumor," as taught by Henley-Cohn (col. 5, ln 10-11).

As per claim 25, Pearson teaches a method of raising the temperature of at least a portion of a tissue structure (para [0059]--"various aspects of the invention is particularly beneficial for use in the treatment of tumors and tumorous tissue by ablative therapies such as RF, microwave, laser and chemical ablation. These and related ablative therapies causes disruption of cell membranes resulting in impedance change in the interstitial fluid but only in the affected tissue with minimal or no changes to the surrounding tissue") located below an interface between a dermal layer and a subdermal layer of skin, wherein the dermal layer has an upper portion adjacent an external surface of the skin and a lower portion adjacent a subdermal region of the skin, the method comprising the steps of:
positioning a device adapted to radiate microwave energy adjacent the external surface of the skin (para [0004]--"An embodiment of the invention provides an impedance controlled tissue ablation apparatus and method that utilizes impedance determinations, such as localized tissue impedance to optimize the delivery of radio-frequency or other electromagnetic energy to a target tissue site");
radiating microwave energy having an electric field component which is substantially parallel to a region of the external surface above the dermal layer (para [0083]--"the alternative conductive pathway can share one or more points in common with the original pathway or be parallel with the original pathway but offset a selectable lateral distance"; [0087]--"impedance sensing members 22m can be arranged in arrays 22a having a variety of geometric arrangements and relationships so as to electrically sample different volumes of tissue 5sv using different conductive pathways");
creating a lesion in the lower portion of the dermal region by heating tissue in the lower portion of the dermal region using the radiated microwave energy (para [0156]--"these and related embodiments provide the benefit of allowing the size, position and shape of the lesion to be precisely controlled and/or titrated in order to meet the therapeutic needs of the target tissue");
removing heat from the skin surface and at least a portion of the upper portion of the dermal layer to prevent the lesion from spreading into the upper portion of the dermal layer (para [0155]--"In an embodiment, the sensor can be selected to measure temperature...a feedback signal from a temperature sensor or temperature calculation device...determines that a desired cell necrosis temperature is exceeded, then an appropriate signal is sent to the controller which then regulates the amount of electromagnetic energy delivered to the electrodes"); and
ceasing the radiating after a first predetermined time, the predetermined time being sufficient to raise the temperature of the tissue structure (para [0175]--"with the use of sensor 324 and feedback control system 329, tissue adjacent to RF electrodes 314 and 316 can be maintained at a desired temperature for a selected period of time without causing a shut down of the power circuit to electrode 314 due to the development of excessive electrical impedance at electrode 314 or adjacent tissue").

However, Pearson does not specifically teach wherein the microwave energy has a frequency which generates a standing wave pattern in the dermal layer, the standing wave pattern having a constructive interference peak in the lower portion of the dermal layer. Henley-Cohn does teach wherein the microwave energy has a frequency which generates a standing wave pattern in the dermal layer, the standing wave pattern having a constructive interference peak in the lower portion of the dermal layer (col. 4, ln 66 - col. 5, ln 11). It would have been obvious to one of skill in the art to combine the standing wave pattern of Henley-Cohn to the system of Pearson to provide an apparatus for treating tissue using microwave energy that preferentially heats a target site (ie: tumor), "without an adverse effect on tissue surround the tumor," as taught by Henley-Cohn (col. 5, ln 10-11).

Claims 1-27 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.